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PATENT

Our Docket No. 3856-4006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Reissue of
Letters Patent 5,556,838**

David J. MAYER et al.

Serial No.: TBA

Filed on: May 19, 1994

Granted on: September 17, 1996

For: **INHIBITING THE DEVELOPMENT OF
TOLERANCE TO AND/OR DEPENDENCE
ON AN ADDICTIVE SUBSTANCE**

Commissioner for Patents
U.S. Patent & Trademark Office
Washington, DC 20231

PRELIMINARY REMARKS

Sir:

Claim 1 of U.S. Patent No. 5,556,838 ("the '838 patent") has been amended.

Claims 3-16 have been added. Accordingly, claims 1-16 are pending in this application.

Examination on the merits is respectfully requested. No new matter has been introduced.

Also submitted herewith, is an Information Disclosure Statement.

**Claims 1-16 in the Reissue Application are Narrower in Scope than the
Original '838 Patent Claims and have Support in the '838 Patent Specification.**

The claims submitted in this reissue application are narrower in scope than the claims issued in the '838 patent. The '838 patent claim one is directed to a "composition" comprising "at least one nontoxic substance that blocks the N-methyl-D-aspartate receptor or a major intracellular consequence of N-methyl-D-aspartate receptor activation" and an addictive substance selected from an enumerated group of materials.

Amended claim 1 is narrower than patent claim 1 of the '838 patent by: (1) limiting the "composition" to a "formulated pharmaceutical composition, (2) limiting the "at least one nontoxic substance that blocks the N-methyl-D-aspartate receptor or a major intracellular consequence of N-methyl-D-aspartate receptor activation" to a "synthetic" substance; and (3) further limiting the "nontoxic" substance in several respects to exclude at least ketamine that was embraced by patent claim 1.

All of the presented claims (amended claim 1 and claims 3-16) are narrower than '838 patent claim one, in the following respects:

(1) all of the claims limit the composition to a "formulated pharmaceutical composition";
(2) all of the claims limit the second, "nontoxic" substance to a synthetic substance; and
(3) all of the claims define the second "nontoxic" substance more narrowly, by either (i) expressly excluding "ketamine, AP-5 and 7-chlorokynurenate" (amended claim 1 and its dependent claims), (ii) limiting the substance that "blocks the N-methyl-D-aspartate receptor" to those that "consist[s] essentially of a morphinan" (claims 3 and 5 and their dependent claims) or (iii) limiting the substance to a member of the "group consisting of dextromethorphan, dextrorphan and pharmaceutically acceptable salts thereof." (claim 4 and its dependent claims.)

Also, claims 4-13 and claims 14-16, as they depend from claims 4 and 5, limit the addictive substance to only some of the members recited in patent claim one.

Each of the limitations recited in amended claim 1 and claims 3 through 16 can be found in the the original '838 patent, for which reissue is now sought, as illustrated below:

1. The "formulated pharmaceutical" limitation in all of the presented claims is expressly disclosed in the '838 patent at column 6, line 6.

Amended claim 1 is narrower than patent claim 1 of the '838 patent by: (1) limiting the "composition" to a "formulated pharmaceutical composition, (2) limiting the "at least one nontoxic substance that blocks the N-methyl-D-aspartate receptor or a major intracellular consequence of N-methyl-D-aspartate receptor activation" to a "synthetic" substance; and (3) further limiting the "nontoxic" substance in several respects to exclude at least ketamine that was embraced by patent claim 1.

All of the presented claims (amended claim 1 and claims 3-16) are narrower than '838 patent claim one, in the following respects:

(1) all of the claims limit the composition to a "formulated pharmaceutical composition";
(2) all of the claims limit the second, "nontoxic" substance to a synthetic substance; and
(3) all of the claims define the second "nontoxic" substance more narrowly, by either (i) expressly excluding "ketamine, AP-5 and 7-chlorokynurenate" (amended claim 1 and its dependent claims), (ii) limiting the substance that "blocks the N-methyl-D-aspartate receptor" to those that "consist[s] essentially of a morphinan" (claims 3 and 5 and their dependent claims) or (iii) limiting the substance to a member of the "group consisting of dextromethorphan, dextrorphan and pharmaceutically acceptable salts thereof." (claim 4 and its dependent claims.)

Also, claims 4-13 and claims 14-16, as they depend from claims 4 and 5, limit the addictive substance to only some of the members recited in patent claim one.

Each of the limitations recited in amended claim 1 and claims 3 through 16 can be found in the the original '838 patent, for which reissue is now sought, as illustrated below:

1. The "formulated pharmaceutical" limitation in all of the presented claims is expressly disclosed in the '838 patent at column 6, line 6.

2. The members of the group from which the addictive substance is selected in claims 3-13 are expressly disclosed in the '838 patent for example, at column 2, lines 56-66, and in patent claim one.

3. The non-toxic synthetic substance as recited in claim 4 ("dextromethrophan, dextrophan, and their pharmaceutically acceptable salts") is expressly disclosed in the '838 patent in the Abstract, and at column 4, lines 51-56, and elsewhere.

4. The class of "morphinans" recited in independent claims 3 and 5 is found, for example, in the '838 patent at col. 4, line 53.

5. The oral dosage form recited in claims 14 and 16 can be found, for example, in the '838 patent specification at Col. 5, lines 41-44 ("Introduction of the composition into the patient can be by way of oral administration . . .").

6. The sustained release form recited in claims 15 and 16 can be found in patent claim 2 and Col. 6, lines 44-50.

Preliminary Remarks
Reissue Application of U.S. Patent No. 5,556,838

Our Docket No. 3856-4006

CONCLUSION:

It is respectfully submitted that the claimed invention is fully supported and not taught or suggested by any of the references of record, and therefore the reissue application is in condition for allowance.

Respectfully submitted,

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Dated: June 15, 2001

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